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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/724,135    11/28/00    MCFARLAND    E    2727.1001-00

021005    HM22/1010  
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EXAMINER

PADMANABHAN, K.

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/724,135

Applicant(s)

McFARLAND, EILEEN LOUISE  
RICE

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. In view of applicant's arguments, the restriction requirement of the previous office action is herein withdrawn, and claims 1-13 will be examined together.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's invention is drawn to a method of determining predisposition to psychosis by measuring the presence of anti-cw antibodies in a sample. However, many dispositions, outside the realm of psychotic disorders may be determined by measuring these antibodies. For example, numerous studies, including Curtin et al., (Am. J. Medical Tech., 1967) Mouro et al. (Blood, 1995), and Bowman et al. (Vox Sang, 1993) disclose the measurement of these antibodies for the determination of hemolytic disease. Therefore, how can the determination of the same antibodies be used to determine completely unrelated disorders? The current state of the art does not enable the undertaking of a method or kit for this purpose. Further, since Cw is relatively rare and no previous correlation has been demonstrated between the measurement of cw antibodies and psychosis, a method attempting to link the two inherently encompasses a great amount of uncertainty, which the current state of the art is unable to

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remedy. In addition, there is insufficient guidance and working examples in the specification to enable one of skill in the art to determine predisposition to psychosis by measuring anti-cw antibodies. The one case study with only 1 subject is grossly insufficient to meet this criterion of enablement. The results from one case study cannot possibly be used as a definitive statement that the method of applicant can be used in all cases and populations to determine predisposition to psychosis. Results of case studies must be readily reproducible, which has not been established in this instance. Especially when considering that only one patient was followed in the case study, the onset of schizophrenia could have occurred by chance and not due to the presence of anti-cw antibodies. In addition, the disclosure of applicant has not enabled the determination of predisposition to all types of psychosis. Since the many psychotic disorders affect the body through different mechanisms that may differ greatly, it is unclear how one could use one method to determine predisposition to all these disorders. Applicant has certainly not elucidated that issue in the specification. Further, applicant has only provided one example with a patient who developed schizophrenia, which is insufficient to enable all types of psychosis. Therefore, undue experimentation would be required of one of skill in the art to practice the invention commensurate with the full scope of the claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the way in which anti Cw antibodies are indicative of predisposition to psychosis. Applicant has not specified the manner in which cw antibodies or correlated to this predisposition. Applicant should recite these correlation steps in the claims.
7. Claim 1 recites the limitations "the mother" and "the presence. There is insufficient antecedent basis for these limitations in the claim. In addition, since the claim does not end in a period, it is unclear if text at the end of the claim has been inadvertently omitted.
8. Claim 5 recites the limitation "the same blood type". There is insufficient antecedent basis for this limitation in the claim.
9. Claim 6 recites the limitation "the presence". There is insufficient antecedent basis for this limitation in the claim.
10. Claims 7-9 are rejected as vague and indefinite because it is unclear if the claims are intended to depend on claim 6 or on claim 8. It is noted that a claim cannot depend on a higher numbered claim or on itself.
11. Claim 10 is rejected as vague and indefinite because it is unclear how one can have a sample of anti-Cw. Does applicant intend to claim a sample containing Cw antibodies?
12. Claim 11 recites the limitations "the diagnosis" and "the presence. There is insufficient antecedent basis for these limitations in the claim.

#### ***Response to Arguments***

13. Applicant's arguments filed July 30, 2001 have been fully considered but they are not persuasive to overcome the rejection under 35 USC 112, first paragraph. Applicant's arguments

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that undue experimentation would not be required to practice the claimed invention is inaccurate. Although undue experimentation would not be required to measure anti-cw antibodies, it would be required to establish a link between those antibodies and a predisposition to psychosis. Even in the one example provided by applicants, a number of years were required before a diagnosis of schizophrenia was made. In addition, the state of the art does not enable the diagnosis of a predisposition to psychosis. As applicant acknowledges, the prior art does not establish a link between anti-cw antibodies and psychosis. If it had, the reference would qualify under the appropriate section of 35 USC 102. Applicant's reliance on the case study present in the specification is insufficient to provide adequate predictability, guidance, and working examples. As discussed previously, applicant has shown the results of one individual possessing anti-cw antibodies who later developed schizophrenia. This result may have occurred by chance. Since a study of many individuals from multiple studies has not been provided, applicant has not enabled the determination of a predisposition to psychosis. Further, applicant's arguments that the effect of the anti-cw antibody and not the mere presence of the antibody is the determining factor is also unconvincing to provide enablement for the recited claims. The presence of the antibody renders the fact that it will exert some effect inherent. If the antibody is present, it will exert some sort of effect.

### ***Conclusion***

Claims 1-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641



October 9, 2001



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641